



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JAN 19 2001

Mr. Jerry Wang  
A&D Engineering  
Director of Engineering and QA  
1555 McCandless Drive  
Milpitas, CA 95035

Re: K002061  
~~Trade Name:~~ A&D Medical TM-2550, 2551, 2560 Vital Sensor Monitor  
Regulatory Class: II (two)  
Product Code: DRT  
Dated: October 20, 2000  
Received: October 23, 2000

Dear Mr. Wang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

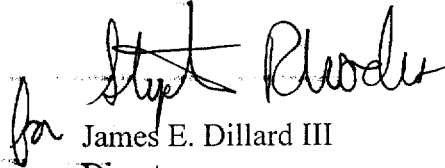
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response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is written in a cursive, flowing style. To the left of the signature, there is a small, handwritten mark that looks like "for".

James E. Dillard III  
Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K002061

Device Name: TM-25xx VITAL SENSOR Monitor

**Indications for Use:**

The TM-2550, TM-2551, and TM-2560 are designed to be a portable automatic sphygmomanometer to measure systolic and diastolic blood pressure and pulse rate by oscillometric method for the general hospital populations. All models ~~also have~~ an IV drip timer to help nurse adjust the speed of the IV drips. TM-2551 and TM-2560 can be programmed to conduct BP measurements at a fixed interval. When measured results exceed upper or lower pre-set limits, alarm would go off for the TM-2551 and TM-2560. TM-2560 is capable of measuring %SpO2 value and pulse rate by pulse oximetry. All models can have an optional printer with a suffix "P" at the end of the model names.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Division of Cardiovascular & Respiratory Devices  
510(k) Number: K002061

Prescription Use X

or

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)